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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/518,020 03/03/00 KAPLAN

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HAMILTON BROOK SMITH AND REYNOLDS, P.C.
TWO MILITIA DR
LEXINGTON MA 02421-4799

EXAMINER

FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/518,020

Applicant(s)

KAPLAN ET AL.

Examiner

Ilesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 14-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Applicant's election of Group I, claims 1-13, and 37-38 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 1-13 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The claims are vague and indefinite in the recitation of "analog". One of skill in the art would be unable to determine the metes and bounds of such a limitation. For example, what constitutes an analog? Without a clear definition as to what an "analog" is one of skill in the art would be unable to replicate the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-11 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Gutnick et al.

The claims are drawn to a composition comprising an antigen and an emulsan.

Gutnick et al. (US Patent 4,311,829) disclose a composition comprising an antigen and an emulsan. Gutnick et al. further disclose a composition wherein the emulsan is secreted from *Acinetobacter Sp.* Gutnick et al. further disclose that the emulsan composition comprises an emulsan analog wherein the analog has a fatty acid chain length of 10-18 carbons (See Entire Document).

It has been noted that the claims in the instant application recite that the composition is an "immunization formulation". However, referring to the composition as a formulation which can be used in immunization is being viewed as intended uses of the composition and therefore, carries no patentable weight when compared to the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutnick et al. further in view of Fino.

The claims are drawn to a composition comprising a polypeptide antigen coupled to keyhole limpet hemocyanin (KLH).

The teachings of Gutnick et al. are set forth above.

Gutnick et al. does not teach of a polypeptide antigen coupled to keyhole limpet hemocyanin.

Art Unit: 1645

Fino (US Patent 5,464,746) teach of polypeptide antigens coupled to carriers such as keyhole limpet hemocyanin (See Entire Document). Fino further teaches that the antigens can be used to generate antibodies (i.e. stimulate an immune response).

Given that 1) Gutnick et al. has taught of a composition comprising an antigen and an emulsan wherein the emulsan is secreted from *Acinetobacter* and that 2) Fino has taught of a polypeptide antigen coupled to a keyhole limpet hemocyanin carrier it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a composition comprising a polypeptide antigen coupled to keyhole limpet hemocyanin. One would have been motivated to make such a composition because it is well known to those skilled in the art that an antigen coupled with a carrier such as KLH increases immunogenicity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

September 10, 2001



MARK NAVARRO
PRIMARY EXAMINER